DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 04, 2009 has been entered.

Priority

2. This application claims priority to Application No. 60/351,698 filed on January 24, 2002 and Application PCT/US03/02347 filed on January 24, 2003, the instant Application appears to add new matter not presented in the prior applications. Specifically, regarding at least the flexible plastic enteral feeding catheter tube. Therefore, the filing date of January 23, 2004 is being accorded to independent claims 7, 12, 30, and their dependents.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification does not appear to specifically disclose a flexible plastic enteral feeding catheter tube.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-14 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Application as filed does not appear to disclose that the enteral feeding catheter tubes are plastic.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7-14 and 30-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "very flexible" in at least claims 7, 12, 30, 36, and 39 is a relative term which renders the claim indefinite. The term "very flexible" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thereby, the flexibility of the catheter tube is rendered indefinite.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 7, 8, 30, 31, 33, 35, 36, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pozzo (US 5,092,847) in view of Ferguson et al. (US 5,637,086).

With regard to claims 7, 30, and 35, Pozzo teaches a catheter and stylet assembly, comprising: a) a catheter tube sub-assembly including a small diameter, very flexible plastic enteral feeding catheter tube having a distal end and a proximal end, said tube having a connector on its proximal end (Fig. 2 tube 14 connector 18, Col. 4 lines 29-32); and b) a first stylet sub-assembly including a primary flexible twisted wire stylet having distal and proximal ends, said first stylet sub-assembly also including a first stylet fitting in which the proximal end of said primary stylet is seated (Fig. 3 stylet 32 hub 34, claim 1 last two paragraphs). Pozzo does not teach using two stylets movable relative to each other to vary the stiffness of the tube in which the second stylet extends into the first stylet fitting. However, Ferguson et al. teach using multiple sylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed (Col. 4 lines 35-37). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a second stylet like stylet 30 in Pozzo because Ferguson et al. teach using multiple sylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed the second stylet would be able to be inserted through lumen 39 of hub 34 and into the catheter. Further, it would have

been obvious to a person of ordinary skill in the art at the time the invention was made to add a second stylet, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, *St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8.

With regard to claims 8 and 31, distal portion 40 of the second stylet fitting would be capable of connecting within the proximal opening 39 of the first stylet fitting. Stylet 32 is retained within portion 40 (Fig. 3).

With regard to claim 33, the catheter is an 8Fr tube with a bullet nose bolus 20 (Fig. 2, Col. 4 line 30).

With regard to claim 36, Pozzo teaches a catheter assembly comprising: a) a catheter tube sub-assembly including a small diameter, very flexible enteral feeding catheter tube having a distal end and a proximal end, said tube having a connector on its proximal end (Fig. 2 tube 14 connector 18, Col. 4 lines 29-32); and b) a stylet sub-assembly including a flexible, twisted wire stylet having distal and proximal ends (Fig. 3 stylet 32 hub 34, claim 1 last two paragraphs). Pozzo does not teach using second wire to vary the stiffness of the tube. However, Ferguson et al. teach using multiple sylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed (Col. 4 lines 35-37). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a second stylet like stylet 30 in Pozzo because Ferguson et al. teach using multiple sylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed. Further, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a second stylet, since it has been held that mere duplication of the essential working

parts of a device involves only routine skill in the art, *St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8.

With regard to claim 39, Pozzo teaches a catheter and stylet assembly, comprising: a) a catheter tube sub-assembly including a small diameter, very flexible enteral feeding catheter tube having a distal end and a proximal end (Fig. 2 tube 14 connector 18, Col. 4 lines 29-32); and b) a first stylet sub-assembly including a primary flexible wire stylet having distal and proximal ends (Fig. 3 stylet 32 hub 34, claim 1 last two paragraphs). Pozzo does not teach using two stylets movable relative to each other to vary the stiffness of the tube. However, Ferguson et al. teach using multiple sylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed (Col. 4 lines 35-37). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a second stylet like stylet 30 in Pozzo because Ferguson et al. teach using multiple sylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed. Further, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a second stylet, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, *St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8.

11. Claims 9 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pozzo (US 5,092,847) and Ferguson et al. (US 5,637,086) as applied to claims 7 and 31 above, and further in view of Preissman et al. (US 6,019,776).

With regard to claims 9 and 32, Pozzo teaches a stylet substantially as claimed. Pozzo does not teach a visible mark formed on the stylet. However, Preissman et al. teach using a

radiopaque mark on a stylet so that it can be monitored during insertion (Col. 5 lines 22-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place a marker on the stylet in Pozzo because Preissman et al. teach that marks aids in observing the position of the stylet within the body. It would be a matter of obvious design choice as to the location of the mark. The mark will be located as desired by the user depending on how they are going to use viewing the mark via fluoroscopy. Ultimately, the mark is still being used to aid the user in knowing the location, within the patient, of the item it is placed on. For this reason, positioning a mark approximately 12" from its stylet connector would have been an obvious expediency in the art.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pozzo (US 5,092,847) and Ferguson et al. (US 5,637,086) as applied to claim 7 above, and further in view of Abrahmson et al. (U.S. Patent 5,382,238).

With regard to claim 10, Pozzo teaches a catheter and stylet assembly substantially as claimed. Pozzo does not teach a catheter with two lumens. However, Abrahamson teaches a catheter tube with two lumens (Col. 3 line 12). This allows a stiffener to be inserted in one lumen leaving the other lumen free for fluid delivery. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a double lumen catheter in the device of Pozzo because Abrahmson et al. teaches using a double lumen catheter and further to insert the stylets into only one of the lumens because this allows a wire stiffener to be inserted and then the catheter can be used in a conventional manner employing two lumens (Col. 4

paragraph 2), stiffening and fluid delivery can occur simultaneously. The catheter is capable for use in enteral feeding.

With regard to claim 11, Pozzo teaches a catheter and stylet assembly substantially as claimed with a bullet nose bolus 20 (Fig. 2). Pozzo does not specifically disclose the catheter tube being a 5 Fr size tube. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made use a 5 Fr tube because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the tube of Pozzo because it still allows for adequate fluid delivery and feeding.

13. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2001/0018576 A1) in view of Pozzo (US 5,092,847), Andersen et al. (US 4,594,074), and Ferguson et al. (US 5,637,086).

With regard to claim 12, Quinn et al. teach a catheter and stylet assembly, comprising: a catheter tube assembly including a unitary flexible plastic enteral feeding catheter tube ([0135]) containing two lumens and a smaller diameter unitary flexible plastic enteral feeding catheter tube containing a single lumen; b) said tube and said smaller diameter tube being connected by a unitary bolus formed independently of said tube and said smaller diameter tube having a side port; c) said enteral feeding catheter tube having a proximal and a distal end, said proximal end having a connector on its proximal end (Fig. 27); and d) said smaller diameter enteral feeding catheter tube containing a single lumen formed separately from said two lumen tube (regarding

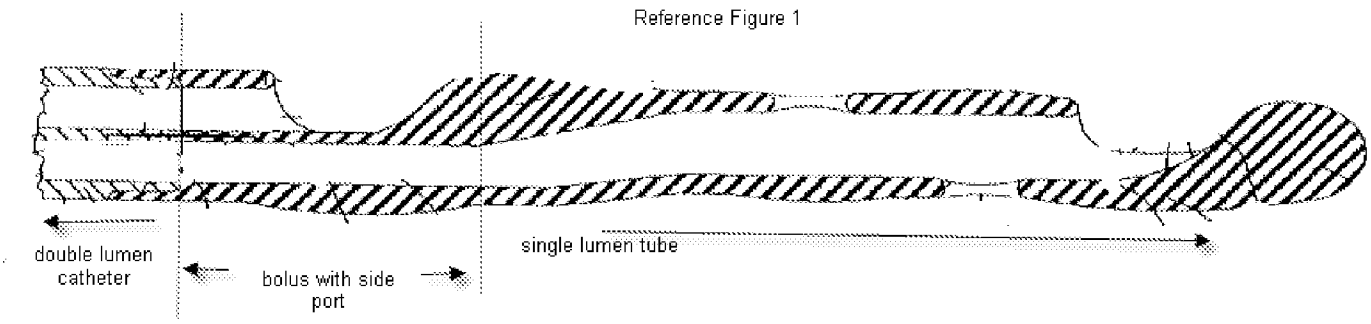
elements a-d see Reference Figure 1 below, the double lumen portion is formed separately of the bolus and single lumen portion as evidenced by the cross-hatching further generally see Fig. 29). The device is capable for use with enteral feeding.

Quinn does not teach using an 8 Fr tube. However, Pozzo teaches a feeding tube available in the art to be 8 Fr (Col. 4 lines25-27). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an 8 Fr tube in Auinn because Pozzo teaches that this size tube is suitable for use for feeding. Further, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made use an 8 Fr tube because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the tube of Quinn because it still allows for adequate fluid delivery.

Quinn teaches the dual lumen tube to be formed separately of the bolus and single lumen tube. Quinn does not teach the bolus to be formed independently of both the double and single lumen tubes. However, Andersen et al. teach a catheter assembly for enteral feeding which uses an intermediate bolus to connect two tubes, the portions of the device are constructed independently of one another (Fig. 7). This would allow for the device to be constructed with varying materials and flexibility depending on where the device will be used. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to for the bolus independently of the tubes in the device of Quinn because Andersen et al. teaches such construction is beneficial and art recognized for use in enteral feeding and would allow for the device to be constructed with varying materials and flexibility depending on where the device

will be used. Further, it would have been obvious to a person of ordinary skill in the art at the time the invention was made construct the pieces separately since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin V. Erlicnman*, 168 USPQ 177, 179.

Quinn does not teach first and second stylet subassemblies. However, Pozzo teaches a catheter with a first stylet sub-assembly including a primary flexible twisted wire stylet having distal and proximal ends, said first stylet sub-assembly also including a first stylet fitting in which the proximal end of said primary stylet is seated (Fig. 3 stylet 32 hub 34, claim 1 last two paragraphs). Pozzo does not teach using two stylets movable relative to each other to vary the stiffness of the tube in which the second stylet extends into the first stylet fitting. However, Ferguson et al. teach using multiple sylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed (Col. 4 lines 35-37). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a second stylet like stylet 30 in Pozzo because Ferguson et al. teach using multiple sylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed the second stylet would be able to be inserted through lumen 39 of hub 34 and into the catheter. Further, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a second stylet, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, *St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8.



With regard to claim 13, Quinn teaches a catheter and stylet assembly substantially as claimed. Quinn does not specifically disclose the catheter tube being a 5 or 6 Fr size tube. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made use a 5 or 6 Fr tube because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the tube of Quinn because it still allows for adequate fluid delivery.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn (US 2001/0018576 A1), Pozzo (US 5,092,847), Andersen et al. (US 4,594,074), and Ferguson et al. (US 5,637,086) as applied to claim 12 above, and further in view of Clegg et al. (US 5,167,627) and Anderson et al. (US 4,594,074).

With regard to claim 14, Quinn teaches an catheter substantially as claimed. Quinn does not teach the catheter to be lubricated. However, Clegg et al. teach lubricating the exterior of the catheter (Col. 7 lines 21-22) which would assist in the insertion of the catheter into the body and Anderson et al. teach using a lubricant within the catheter to facilitate movement of the stylet within the catheter (Col. 6 lines 15-19). It would have been obvious to a person of ordinary skill

in the art at the time the invention was made to lubricate the catheter in Quinn as in Clegg et al. and Anderson et al. because this facilitates insertion of the catheter within the body and movement of the stylet within the catheter.

15. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pozzo (US 5,092,847 and Ferguson et al. (US 5,637,086) as applied to claim 33 above, and further in view of Clegg et al. (US 5,167,627) and Anderson et al. (US 4,594,074).

With regard to claim 34, Pozzo teaches an enteral feeding catheter substantially as claimed. Pozzo does not teach the catheter to be lubricated. However, Clegg et al. teach lubricating the exterior of the catheter (Col. 7 lines 21-22) which would assist in the insertion of the catheter into the body and Anderson et al. teach using a lubricant within the catheter to facilitate movement of the stylet within the catheter (Col. 6 lines 15-19). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to lubricate the catheter in Pozzo as in Clegg et al. and Anderson et al. because this facilitates insertion of the catheter within the body and movement of the stylet within the catheter.

16. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pozzo (US 5,092,847 and Ferguson et al. (US 5,637,086) as applied to claim 36 above, and further in view of Meier et al. (US 6,458,106 B1).

With regard to claim 37, Pozzo teaches an enteral feeding catheter substantially as claimed. Pozzo does not teach the distal end of the catheter to be coiled. However, Meier et al. teach using a coil at the distal end of a catheter to anchor it within the jejunum (Col. 9 lines 64-

67) the stylet would be able to uncoil the coiled section as it is extended through the catheter. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a coiled distal section in the catheter of Pozzo because Meier et al. teach this to anchor the catheter within the jejunum for effective feeding.

17. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pozzo (US 5,092,847, Ferguson et al. (US 5,637,086), Abrahmson et al. (U.S. Patent 5,382,238) as applied to claim 11 above, and further in view of Osborne (US 2001/0053890 A1).

With regard to claim 38, Pozzo teaches an enteral feeding catheter substantially as claimed. Pozzo does not teach the length of the catheter to be 60 inches. However, Osborne teaches it is beneficial to locate the feeding catheter in the jejunm so as to bypass the stomach while feeding ([0004]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to locate the distal end of the catheter in the jejunum in Pozzo because Osborne teaches it is beneficial to locate the feeding catheter in the jejunm so as to bypass the stomach while feeding. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to use a catheter with a length of 60 inches because Applicant has not disclosed that such a length provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with catheter of Pozzo and Osborne because the feeding catheter would be located in the jejunum. Further, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Depending on the patient the length of the catheter may be varied so as to locate the catheter in the correct location.

Response to Amendment

18. The amendments to the claims and specification have been entered.

Response to Arguments

19. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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